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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,215	05/17/2001	Peter Huub Gerard Maria Kirchholtes	D/98409 US	7592

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EXAMINER

JIANG, SHAOJIA A

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/787,215

Applicant(s)

KIRCHHOLTES ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Office Action is a response to Applicant's response filed on January 3, 2002 in Paper No. 8. Currently, claims 1-7 and 9-18 are pending in this application.

Applicant's remarks filed January 3, 2002 in Paper No. 8 with respect to the rejection of claims 9-18 made under 35 U.S.C. 102(b) as being anticipated by Haan De et al. (WO 98/47517) for reasons of record stated in the Office Action dated July 31, 2001 have been considered and are found persuasive to remove this particular rejection since Haan De et al. is not prior art in view of the foreign priority under 35 U.S.C. 119(a)-(d) claimed by applicants.

### ***Claim Objection***

Claims 12-15 and 17-18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is well settled that recitation of an inherent property of a composition or method will not further limit claims drawn to a composition or method. In the instant case, for example, "the shelf life" of the compositions herein in claims 12-15 and 17-18 is an inherent property of the composition herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "highly pure" in claims 1-4 renders claims 1-5 indefinite. The expression "highly pure" is not defined by the specification and claims. Therefore, the scope of claims is indefinite as to the purity of (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one (tibolone) in the composition herein encompassed .

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Sas et al. (EP 389035 A1) for reasons of record stated in the Office Action dated July 31, 2001.

Sas et al. discloses a pharmaceutical composition comprising highly pure (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one (tibolone). See abstract and Examples 1-8. Sas et al. also discloses a dosage unit comprising a pharmaceutically suitable solid carrier and the 97.2% pure (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg (see

Example 6, form I in an amount of 2.5 mg obtained in example 2 having purity 97.2%).

Thus, Sas et al. anticipates the claimed invention.

Applicant's remarks filed on January 3, 2002 with respect to this rejection of claims 1-3, 7, and 9 made under 35 U.S.C. 102(b) have been fully considered and but are not deemed persuasive to remove the rejection as discussed below.

Applicant argues that the presently claimed invention is not anticipated by Sas because the instant composition of (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one comprising (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, the impurity, in an amount less than 0.5%, 0.25%, or 0.1% by weight whereas Sas is silent about the presence of any impurities in the composition. However, the expression "less than 0.5%, 0.25%, or 0.1% by weight" in the instant claims is seen to merely limit the claims to any amount less than 0.5%, 0.25%, or 0.1% by weight including 0%. Thus, the composition of Sas comprising 0% by weight of impurity herein is within the instant claim. Therefore, the instant invention is seen to be anticipated by Sas.

Therefore, said rejection is adhered to.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. and Van Vliet et al. for reasons of record stated in the Office Action dated July 31, 2001.

Applicant's remarks filed on January 3, 2002 with respect to this rejection of claims 4-6 made under 35 U.S.C. 103(a) have been fully considered and but are not deemed persuasive to remove the rejection for the following reasons.

Applicant argues that the presently claims are not rendered obvious by Sas because the instant composition of (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one, comprising (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, the impurity, in an amount less than 0.5 by weight whereas Sas does not disclose this particular impurity in the composition. However, as discussed above, the expression "less than 0.5% by weight" in the instant claims is seen to merely limit the claims to any amount less than 0.5% by weight including 0%. Thus, the composition of Sas comprising 0% by weight of the impurity herein is within the instant claim. Moreover, Vliet et al. and discloses that the instant composition of (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one comprising (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, the impurity herein, in an amount less than 1%. See page 113 the last line of the 1st paragraph in the right column. Thus, the composition of Vliet et al. is also within the instant claim.

For the above stated reasons, the claimed invention is clearly obvious in view of the prior art. Therefore, said rejection is adhered to.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sas et al. (EP 389035 A1).

Sas et al. discloses a dosage unit comprising a pharmaceutically suitable solid carrier and the 97.2% pure ( $7\alpha$ ,  $7\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-5(10)-en-20-yn-3-one in an amount of less than 2.50 mg. See abstract and Examples 1-8.

Sas et al. does not expressly disclose that the dosage unit comprises pure ( $7\alpha$ ,  $7\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount of 1.25 mg, 0.625 mg or less and the impurity, ( $7\alpha$ ,  $7\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, in an amount of 5%, 3% 2% or less by weight. Sas et al. does not also expressly disclose that the shelf life period of these compositions herein is 6 months, 1 year, 1.5 years and 2 years.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to prepare the compositions herein comprising pure ( $7\alpha$ ,  $7\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount of 1.25 mg, 0.625 mg or less and the impurity, ( $7\alpha$ ,  $7\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-

3-one, in an amount of 5%, 3% 2% or less by weight and to expect the shelf life of these compositions to be 6 months, 1 year, 1.5 years and 2 years.

One having ordinary skill in the art at the time the invention was made would have been motivated to prepare the compositions herein comprising pure (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount of 1.25 mg, 0.625 mg or less and the impurity, (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one, in an amount of 5%, 3% 2% or less by weight since the compositions comprising pure (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount of less than 2.50 mg are known according to Sas et al. Therefore, one of ordinary skill in the art would have found it obvious to prepare the compositions herein comprising pure (7 $\alpha$ , 7 $\alpha$ )-17-hydroxy-7-methyl-19-nor-17-pregn-4-en-20-yn-3-one in an amount of 1.25 mg, 0.625 mg or less because the optimization of amounts of active agents to be administered is considered well within the skill of artisan, involving merely routine skill in the art (see *In re Aller*, 105 USPQ 233). Additionally, the shelf lives herein of the compositions are expected since they are the inherent property of the composition.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Applicant's examples 1-6 in the specification at pages 6-9 have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention but are not deemed persuasive. The results on the preparation of the compositions herein and their storage time are expected as taught and suggested by



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the cited prior art herein. Therefore, the results herein are clearly expected and not unexpected based on the cited prior art. Expected beneficial results are evidence of obviousness. See MPEP § 716.02(c). Moreover, the results herein are not seen to provide clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no side-by-side comparison with the closest prior art. Therefore, the evidence presented in specification herein is not seen to support the nonobviousness of the instant claimed invention over the prior art.

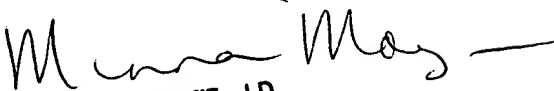
In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Shaojia A. Jiang, Ph.D.  
Patent Examiner, AU 1617  
January 31, 2002

  
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